IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON DIVISION

CHRISTINE JANKOWSKI, et al, Plaintiffs, v. ZYDUS PHARMACEUTICALS USA, INC. and DOES 1-50, Inclusive., Defendants.	DOCKET NO.: 3:20-cv-2458-MAS-TJB Judge: Michael A. Shipp Magistrate Judge: Tonianne J. Bongiovanni

MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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Pursuant to Fed. R. Civ. P. 12(b)(6), Zydus Pharmaceuticals USA, Inc. ("Zydus") submits this Memorandum of Law in support of its Motion to Dismiss Plaintiffs' Second Amended Complaint ("SAC") against Zydus.

I. PRELIMINARY STATEMENT

This is a pharmaceutical product liability action in which 201 plaintiffs allege that they sustained bodily injuries as a result of their (or their spouses and/or decedents) use of the prescription drug amiodarone hydrochloride ("amiodarone"), a generic anti-arrhythmic heart medication manufactured and distributed by defendant Zydus. This action is not the first lawsuit filed by many of the plaintiffs. In fact, 174 plaintiffs, represented by the same counsel as here, have multiple actions pending simultaneously in other jurisdictions against other manufacturers of amiodarone, for the same injuries brought here.

Numerous plaintiffs here brought an identical action with the same allegations in California against 11 generic manufacturers of amiodarone, including Zydus, the brand-manufacturer, Wyeth Pharmaceuticals, Inc. ("Wyeth"), and wholesale distributor McKesson Corporation. That lawsuit was dismissed for lack of personal jurisdiction of over 460 non-California resident plaintiffs and upheld by the California Court of Appeals. The California court subsequently dismissed the California plaintiffs' action as preempted in two separate orders (as to plaintiffs'

second amended complaint and third amended complaint) and as legally deficient and insufficiently pled.

An identical multi-plaintiff action, and one in which this Court relied in its Memorandum Opinion dismissing plaintiffs' First Amended Complaint ("FAC") [ECF No. 24], was filed against another generic manufacturer of amiodarone (Taro Pharmaceuticals USA, Inc.) in its home state of New York. The Southern District of New York dismissed that action on a 12(b)(6) motion as preempted, failing to state a cognizable claim, and as insufficiently pled. *Frei v. Taro Pharm. U.S.A., Inc*., 2020 WL 1165975 (S.D.N.Y. Mar. 10, 2020). The Second Circuit subsequently upheld the District Court's finding. *Frei v. Taro Pharm. U.S.A., Inc*., Case No.: 20-1208, Doc. 105-1 (2d Cir. 2021)(*Summary Order*). Five federal Circuit Courts of Appeal have affirmed six dismissals of amiodarone lawsuits brought by the same plaintiffs' counsel as here, three of which were this year.[1]

Five months ago, this Court granted Defendant's motion to dismiss Plaintiffs' FAC. [ECF No. 24] The Court held that plaintiffs did not identify a parallel state law requiring Zydus to make medication guides available and as such, their failure to

[1] *See Frei v. Taro Pharmaceuticals USA, Inc*., Case No.: 20-1208, Doc. 105-1 (2d. Cir. 2021) (*summary order*); *Cook v. Par Pharmaceutical, Inc*., 849 Fed. Appx. 809 (11th Cir. 2021); *Collette v. Wyeth Pharmaceuticals, Inc*., -- Fed. Appx. --, 2021 WL 3126742 (9th Cir. 2021). *Bean v. Upsher-Smith Pharm., Inc*., 765 F. App'x 934 (4th Cir. 2019); *McDaniel v. Upsher-Smith Labs., Inc*., 893 F.3d 941 (6th Cir. 2018); *Tutwiler v. Sandoz Inc*., 726 F. App'x 753 (11th Cir. 2018).

warn and design defect claims against Zydus were preempted. *Id*. at 7-9. The Court also found plaintiffs' off-label marketing claims to be preempted and that plaintiffs' negligence per se claim was not based on any state law. *Id*. at 11-13. The Court further held that plaintiffs' claims for failure to report adverse events to the FDA and fraud were conclusory and speculative and were insufficient to support a claim under the federal rules. *Id*. at 10, 13-14.

Plaintiffs' second amended complaint ("SAC") has abandoned the causes of action for negligent marketing and sale, negligence per se, manufacturing defect, and fraud/deceit. [ECF No. 27]. Plaintiffs' SAC is now limited to causes of action for (1) Strict Products Liability – Failure to Warn, (2) Negligence – Failure to Warn, and (3) Wrongful Death. These causes of action are premised on allegations that the FDA-approved warnings were not provided to plaintiffs' prescribing physicians; that Zydus was responsible for "misleading" information on the Physician Desk Reference (PDR) and Epocrates applications; that Zydus took advantage of Wyeth's (brand manufacturer) off-label promotional activities and did not correct the information; and that Zydus failed to provide plaintiffs' with a medication guide. *Id*.

Plaintiffs have added no new allegations or facts that would support the causes of action alleged and have contradicted their own allegations throughout the entire complaint. Plaintiffs allege that Zydus failed to provide FDA warning to plaintiffs'

prescribing physicians and at the same time allege that the prescribing physicians relied upon PDR and Epocrates in prescribing amiodarone.

There is no federal or state obligation to physically provide a physician with the label or warnings. There is no federal or state obligation to ensure that physicians obtain and read the label warnings. The manufacturer of a generic drug, such as Zydus, is obligated to mirror the approved FDA label, which is not raised as an issue in dispute in the SAC. The manufacturer is obligated to include the label and warnings as part of the package insert, again not raised as an issue in dispute in the SAC.

There is no allegation that the treating/prescribing physicians wrote a prescription specifically for the Zydus version of amiodarone. Nor that the physicians' relied specifically on the Zydus warning or label. Knowledge of the drug's use and risks is an obligation of the learned intermediary who has multiple resources available to inform the physician of such information, i.e., the FDA website, DailyMed website, PDR etc.

Plaintiffs further allege that Zydus should have corrected "misleading" "statements" or "information" made in the PDR and Epocrates apps, yet in the 380-page complaint, plaintiffs fail to identify a single statement Zydus "made" on the PDR or Epocrates applications, or any off-label statement Zydus "made" anywhere. The only Zydus related connection that plaintiffs cite is a publicly available

photograph of an amiodarone tablet. A photograph of a pill does not convey any warnings, statements or off-label promotional material. As with the first amended complaint, which this court dismissed, plaintiffs' again assert allegations that are speculative, conclusory and non-specific.

Plaintiffs argument that Zydus did not provide FDA warnings to the PDR assumes that there is a legal obligation to have done so. There is no legal obligation under state or federal law. Moreover, the PDR site does not identify a drug by each individual manufacturer, rather it provides a drug summary and label for each drug that has been approved by the FDA.[2] Amiodarone, the drug at issue in this action, has had over a dozen generic manufacturers. The PDR does not identify each generic manufacturer, but instead provides the generic FDA-approved drug information since all manufacturers are required to have the same label.[3]

Despite that this Court dismissed the plaintiffs' previous medication guide related claim based on preemption, plaintiffs have renewed these claims in the amended complaint with no new allegations. Plaintiffs' again allege that Zydus had a duty provide medication guides to plaintiffs. *See* Pltfs SAC at ¶¶ 167, 191. This Court has already held that the regulatory text does not obligate a manufacturer to

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[2] See PDR website at https://www.pdr.net/drug-summary/Amiodarone-Hydrochloride-Injection-amiodarone-hydrochloride-3234.8358 (last visited October 27, 2021)

[3] *See* FDA Orange Book, Approved Drug Product List for Amiodarone, 2015, attached as Exhibit H.

provide medication guides to plaintiffs. [ECF No. 24 at 7]. Accordingly, this Court should again hold that these allegations are preempted.

II. STATUTORY AND REGULATORY FRAMEWORK

The Food, Drug & Cosmetic Act ("FDCA") governs the approval and labeling of prescription drugs in the United States. The FDA implements the FDCA by, *inter alia*, promulgating detailed requirements for pharmaceutical labeling and use; examining proposed drug products for compliance with those requirements before they may enter the market; and ensuring that products already on the market continue to meet those requirements. *See generally* 21 U.S.C. §§ 371-372.

Pursuant to the FDCA and its implementing regulations, a manufacturer seeks FDA approval to market a new drug by filing a New Drug Application (NDA). The manufacturer is considered the innovator. In support of the NDA, the manufacturer is required to demonstrate that the drug is safe and effective for its intended indications, that the labeling proposed is accurate and adequate, and that it will accompany the product. *See* 21 U.S.C. § 355 (a), (d), (e).

Once an innovator's drug has been approved through this rigorous procedure, generic versions of that same drug may be approved through a more abbreviated procedure added to the FDCA in a statutory amendments known by the name of their

congressional sponsors "Hatch-Waxman."[4] *See id*. § 355(j). A generic manufacturer seeks approval to market a generic version by filing an Abbreviated New Drug Application (ANDA). The hallmark of Hatch-Waxman is "sameness." *Id*. at 613. The ANDA will be approved if a generic applicant can demonstrate that, among other things, the proposed generic drug is bio-equivalent to a previously-approved brand-name drug; the applicant need not, independently, prove the generic drug's safety and effectiveness. *See, e.g*., *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). In its ANDA submission the generic must demonstrate that the labeling, including all documentation accompanying the drug is **identical** to the FDA-approved labeling for the brand-name or innovator drug. 21 U.S.C. § 355(j) (2) (A). Generic drug manufacturers are not permitted to change their labeling or deviate from the brand-name or innovator drug's labeling. Generic drug labels can be changed only to incorporate revisions approved by the FDA for the brand label. *Mensing*, 564 U.S. at 614-15.[5]

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[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[5] Pursuant to the FDCA framework, the FDA must regulate and approve all prescription-drug labeling. *See* 21 C.F.R. § 314.105 (c). The FDA has promulgated dozens of pages of detailed regulations describing, among other things, the information and warnings that must be provided by drug manufacturers, covering such matters as the substantive information that must be included (e.g., directions for use, id. § 201.5, ingredient information, *id*. § 201.10, the product's contraindications, *id*. § 201.57(a) (9)), and the appearance and arrangement of that information (e.g., the precise location where an expiration date should appear on a prescription label, *id*. § 201.17, and the font size and margins of labels and warning documents, *id*. §§ 201.57(d), 208.20). *See generally* 21 C.F.R. Parts 201, 208 (labeling regulations).

For certain drugs, such as amiodarone, the drug at issue in this lawsuit, the FDA has required that all those in the distribution chain – manufacturers, distributors and dispensers, must provide a medication guide for distribution to the patients. The regulations obligate the drug manufacturer to make available to distributors, pharmacies/dispensers the guide either by providing copies of the guide or by providing the means to produce them. *See* 21 CFR §208.24 (c).

The medication guide is a document drafted by the innovator and submitted to the FDA for approval and is part of the NDA. In its ANDA, a generic manufacturer, such as defendant Zydus, must demonstrate that it will has formulated and filed an **identical** medication guide. There is no discretion in the substantive content. Pharmacies/dispensers are then required to provide the medication guide to the consumer when the medication is dispensed. *See* 21 CFR §208.24(e).

The FDA expressed the view that the Medication Guide rule would not "alter the duty, or set the standard of care for manufacturers[.]"*See* Final Rule, Prescription Drug Product Labeling; Medication Guide Requirements ("Final Rule"), 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998).

A. Regulatory History of Zydus' Amiodarone.

Warnings associated with amiodarone were first approved for the brand manufacturer, Cordarone®, in 1985. *See* Plaintiffs' SAC at ¶ 166. Since 1985, the Cordarone® label has included the same black box warning about the risks of

pulmonary toxicity and also warned about pulmonary fibrosis.[6] The amiodarone label also warned about pulmonary fibrosis and toxicity and had the same black box warning since it was required to mirror the Cordarone® label.[7] This means that the same side-effects plaintiffs alleged they suffered from amiodarone, have been warned about for the last 35 years.

Amiodarone hydrochloride is a prescription pharmaceutical product indicated for treatment of recurrent ventricular arrhythmias (recurrent ventricular fibrillation and recurrent hemodynamically unstable ventricular tachycardia) when other treatments are ineffective or have not been tolerated. It was first manufactured and sold by Wyeth under the brand name Cordarone® in 1985. Plaintiffs assert they were prescribed a 200 mg (except for the Thomas plaintiffs who allege 400 mg) dose of amiodarone tablets for treatment of atrial fibrillation. FAC ¶¶ 1-151, sub.(d).

The FDA approved Zydus' Abbreviated New Drug Application ("ANDA") permitting it to manufacture and sell amiodarone, the generic version of Cordarone®, on March 30, 2001.[8] Zydus was required to submit an ANDA (#79-029) to the FDA, demonstrating bioequivalence to Cordarone® and proposed

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6 *See* 1985 Approved Labeling Package Insert for Wyeth's Cordarone®, Application Number 18-972, attached as **Exhibit G**, page 10, 21. The Court may take judicial notice of public records and government websites in deciding a Motion to Dismiss. *See* Fed. R. Evid. 201.

7 *See* Zydus' Label and Medication Guide, attached as **Exhibit F.**

8 *See* Zydus' FDA Approval Letter, dated September 16, 2008, attached as **Exhibit E**.

labeling that was materially identical to the Cordarone® labeling. 21 U.S.C. §355(j)(2)(A). The FDA reviewed and approved the proposed labeling, determining it was materially identical to Cordarone®. Federal law required Zydus to keep the labeling, which as of 2008 included a patient-directed Medication Guide, and design of their ANDA-approved amiodarone products consistent with the approved labeling and design for Cordarone®. *Mensing*, 564 U.S. at 624-25.[9]

III. PROCEDURAL HISTORY

This action was originally filed by 191 plaintiffs on March 6, 2020. [ECF No. 1]. The First Amended Complaint ("FAC") was filed on July 10, 2020 adding ten additional plaintiffs for a total of 201 plaintiffs. [ECF No. 8] Defendant filed a Motion to Dismiss Plaintiffs' FAC on October 2, 2020. [ECF No. 11]. This Court granted Defendant's Motion to Dismiss in its entirety on May 28, 2021 with leave the amend. [ECF No. 24, 25]. Plaintiffs filed their Second Amended Complaint ("SAC") on June 21, 2021. [ECF No. 27]. The parties entered into a stipulation extending Defendant's time to answer, move or otherwise respond to the SAC until October 29, 2021. [ECF No. 34]. This motion is timely made.

[9] *See* Zydus' Amiodarone Prescribing Information and Medication Guide, attached as **Exhibit F**, which warn about the same symptoms and injuries alleged by plaintiffs.

IV. LEGAL ARGUMENTS

A. PLAINTIFFS' ACTION FOR NEGLIGENCE IS SUBSUMED BY THE NEW JERSEY PRODUCTS LIABILITY ACT

Plaintiffs' causes of action for negligence (Count II) must be dismissed because it is subsumed by New Jersey's Product Liability Act (the "NJPLA") . While New Jersey does not recognize strict liability action because of the application of NJPLA, only plaintiffs' allegations in Counts I, for Strict Liability – Failure to Warn, allege conduct for which plaintiffs may recover under New Jersey law. Count II, for Wrongful Death, should be dismissed because it is derivative of other causes of action that should be dismissed.

Each of the plaintiffs relies on the NJPLA to govern their action for failure to warn. "The NJPLA generally subsumes common law product liability claims, thus establishing itself as the sole basis of relief under New Jersey law available to consumers injured by a defective product." *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991); accord, e.g., *Clements v. Sanofi-Aventis*, U.S., Inc., 111 F. Supp. 3d 586, 596 (D.N.J. 2015) (the NJPLA is the "sole method to prosecute a products liability action.") (citations omitted); *Durkin v. Pacar*, No. 10-2013, 2010 WL 4117110, at * 5 (D.N.J. Oct. 19, 2010) ("[I]f a claim falls within the scope of the PLA, the sole method to prosecute the claim is under the Act.") (citation omitted); *Smith v. Depuy Orthopaedics, Inc.*, No. CIV.A. 11-4139 JAP, 2013 WL 1108555, at *11 (D.N.J. Mar. 18, 2013), aff'd in part, 552 F. App'x 192 (3d Cir.

2014) (finding negligence and fraud claims in a medical device products liability action as subsumed by the NJPLA).

Product liability actions are defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory of the underlying claim, except for actions caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3). "Thus, New Jersey law no longer recognizes breach of implied warranty, negligence, and strict liability as viable separate claims for harm deriving from a defective product." *Clements*, 111 F. Supp. 3d at 596–97.

Courts in this district have consistently dismissed common law claims, including common law fraud claims, when the gravamen of those claims is harm caused by a product. *See, e.g.*, *Chester v. Boston Sci. Corp.*, No. 16-02421 (FLW), 2017 WL 751424 (D.N.J. Feb. 27, 2017) (dismissing counts for implied warranty, consumer fraud, deceit and fraudulent concealment, and negligent misrepresentation as subsumed by the NJPLA); *Kury v. Abbott Labs., Inc.*, No. 11-803 (FLW), 2012 WL 124026, at *5 (D.N.J. Jan. 17, 2012) (dismissing claims for breach of implied warranty and fraudulent concealment as subsumed by NJPLA); *Delaney v. Stryker Orthopaedics*, No. 08-03210 (DMC), 2009 U.S. Dist. LEXIS 16865, at *19-20 (D.N.J. Mar. 5, 2009) (dismissing consumer fraud claim as subsumed by NJPLA). Plaintiffs here may only bring claims for defective manufacture, defective design and inadequate warning. N.J.S.A. § 2A:58C-1(b)(3).

Plaintiffs' action should be dismissed because as a matter of law the New Jersey Products Liability Act ("NJPLA") is the sole recourse for plaintiffs and the causes of action are subsumed within the NJPLA.

B. AS A MATTER OF LAW ZYDUS' LABEL WAS APPROVED AND WARNINGS WERE ADEQUATE.

Because an action for failure to warn against a generic manufacturer, based on the sufficiency or accuracy of an FDA-approved label, is preempted under *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), plaintiffs do not challenge the content of the label but rather allege that plaintiffs' prescribing physicians never received it without any legal or factual basis for this allegation.[10] The FDA approved Zydus' amiodarone in 2008, along with the label. The "pharmaceutical warning is presumed to be adequate as a matter of law if it is FDA-approved." *Nelson v. Biogen Idec, Inc.*, No. CV127317JMVMF, 2018 WL 1960441, at *9 (D.N.J. Apr. 26, 2018).

In New Jersey, the NJPLA governs the duty of prescription drug manufacturers to provide warnings about the risks and incorporates the learned intermediary doctrine. In the prescription drug context, "[t]his means that the duty to warn is owed to the prescribing physician rather than the patient." Id. at *9. All other plaintiff jurisdictions follow the learned intermediary doctrine. *See* **Exhibit C**.

[10] Plaintiffs acknowledge that Zydus' amiodarone was approved by the FDA in September 2008. See Pltfs SAC ¶ 177. And plaintiffs have not challenged the content of the warnings only contending that the warnings were not "provided" to the prescribing physicians. Id. at ¶¶ 177, 180, 183, 190, 192, 199.

Yet, plaintiffs' have now alleged for the first time that their prescribing physicians never received Zydus' warnings. There is no dispute that the Medication Guide as well as the label were FDA-approved at all times, and under NJ law, the warnings was adequate. See *Seavey v. Globus Med., Inc.*, No. CIV. 11-2240 RBK/JS, 2014 WL 1876957, at *10 (D.N.J. Mar. 11, 2014) ("In the case of certain prescription drugs and medical devices, a manufacturer satisfies its duty to warn by providing the prescribing physician with information about the dangers of the drug or device.").

Plaintiffs contention that their physicians were not "learned" because their physicians never "received" a black box warning and were ignorant of the product risks is not supported by the law. It is widely accepted and recognized that when the warnings in the package insert are adequate as a matter of law, the manufacturer has satisfied its duty and is not subject to liability. *See, e.g., Guarino v. Wyeth, LLC,* 719 F.3d 1245, 1250 (11th Cir. 2013) ("Pharmaceutical manufacturers discharge their duty to warn the learned intermediary by way of a package insert which accompanies each vial of [medicine]." (citing *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997)); *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 287 (S.D.N.Y. 2009) ("Because all of the alleged side effects described by [plaintiff] are specifically indicated as potential side effects in tramadol's package insert, the warning is adequate as a matter of law.").

The package insert is "the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals." The FDA "requires manufacturers to accompany each package of prescription drugs with a package insert[.]" *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1054 (Wash. 1989); see 21 U.S.C. § 355(b)(1)(A)(vi); 21 U.S.C. § 321(m); 21 C.F.R. § 201.100(d); 21 C.F.R. § 201.57. If a package insert, containing adequate warnings, accompanies the medication, the manufacturer has satisfied its duty to warn. *Sherman v. Pfizer, Inc.*, 440 P.3d 1016, 1024-25 (Wash. Ct. App. 2019) ("[A] drug manufacturer's duty to warn is limited to providing a package insert that accompanies the product.") (citations omitted); see Restatement (Second) of Torts § 402A, cmt. k (unavoidably unsafe products must be "accompanied by proper directions and warning") (emphasis added).

As a matter of law, in prescription drug cases "when 'a warning specifically mentions the circumstances complained of, the warning [label] is adequate as a matter of law.'" *Murthy v. Abbott Laboratories*, 847 F.Supp.2d 958,968 (S.D. Tex. 2012), *citing McNeil v. Wyeth*, 462 F.3d 364,368 (5th Cir. 2006).

A manufacturer that provides a proper warning "may reasonably assume that the physician will exercise his informed judgment in the patient's best interests." *See, In re Accutane Litigation*, No. 271, 2016 WL 5958375 at *5 (N.J. Super. Law Div. Oct. 12, 2016); *In re Accutane Litigation*, No. 271, 2016 WL 355843 at *5 (N.J.

Super. Law Div. Jan. 29, 2016); *Cooper v. Bristol-Myers Squibb Co*., C.A. No. 07-885 (FLW), 2013 WL 85291 at *7 n.14 (D.N.J. Jan. 7, 2013) (applying Alabama law); *Ferrara v. Berlex Laboratories, Inc*., 732 F. Supp. 552, 555 (E.D. Pa. 1990), aff'd without opinion 914 F.2d 242 (3d Cir. 1990) (applying Pennsylvania law);

Since it is conceded in the case at bar that the label was adequate, the only issue raised by the plaintiffs is whether their respective physicians knew of the contents of the label. There is no authority that the manufacturer must directly provide to each physician a copy of the label or ensure it is read.

However, the case law is replete with decisions in which the Courts have recognized the responsibility of the physician to read the label and prescribing information as well as noting where the source of that information can be obtained.[11] A prescribing physicians' failure to read the prescribing information can defeat a claim for failure to warn. There is no reported decision that a physician is excused from failing to read the label based on an allegation that it was not physically provided directly to the physician. In the case at bar there is no allegation that the

[11] *Accord Lord v. Sigueiros*, 2006 WL 1510408, at *3 (Cal. Super. April 26, 2006) (undisputed evidence "is sufficient to make a prima facie showing that an element (causation) of each of the causes of action alleged against it cannot be established; in particular . . . [the prescriber] admits that he had not read the [drug] label before prescribing it to the decedent"), aff'd, 2007 WL 4418019, at *4 (Cal. App. Dec. 19, 2007) (no causation where the prescriber "did not review the Physicians Desk Reference"); *Contreras v. Boston Scientific Corp*., 2016 WL 1436682, at *3 (S.D.W. Va. April 11, 2016) (same) (applying California law); *Hexum v. Eli Lilly & Co*., 2015 WL 4943959, at *6-7 (C.D. Cal. Aug. 18, 2015) (granting directed verdict where there was "no proof beyond speculation that [the prescriber] read [the drug's] label before prescribing it"); *Tucker v. Wright Medical Technology, Inc.*, 2013 WL 1149717, at *16 (N.D. Cal. March 19, 2013) ("[w]here the physician did not read the warnings, adequacy is irrelevant").

label did not exist, nor that Zydus impeded or obstructed the FDA from publishing the label.

In *Conte v. Wyeth, Inc*., 85 Cal. Rptr.3d 299 (Cal. App. 2008), unlike in the case at bar, there were allegations of inadequate warnings and the court only had to consider innovator liability because the prescriber never read the generic labeling. Regarding the "failure to read", the court noted:

> There can be no proximate cause where, as in this case, the prescribing physician did not read or rely upon the allegedly inadequate warnings promulgated by a defendant about a product. . . . [B]ecause the prescribing physician testified unequivocally that he neither read the allegedly inadequate warning label nor relied on information provided by [defendant's] representatives before he prescribed the drug to his patient, the adequacy of [those] warnings is irrelevant to the disposition of this case. Such is the case here
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> *Id*. at 319 (citations and quotation marks omitted). (because it was dealing with a brand, the brands often have representatives meeting with physicians unlike generic manufacturers).

In *Perez v. Wyeth Laboratories Inc*., 734 A.2d 1245, 1261 (N.J. 1999), the New Jersey Supreme Court recognized that "a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine if the prescribing physician . . . did not read the warning at all." *Id*. at 1261. Thus, "under New Jersey law, the inadequacy of a warning cannot be the proximate cause of an injury where there is an intervening cause, that is, that the physician either did not read the warning, or had independent knowledge of the risks." *Hrymoc v. Ethicon, Inc*., ___ A.3d ___, 2021 WL 787039,

at *22 (N.J. Super. App. Div. March 2, 2021) (citing *Perez*) a prescribing physician . . . did not read the warning at all." *Id*. at 1261. *In re Alloderm Litigation*, 2015 WL 5022620, at *3 (New Jersey Super. Law Div. Aug. 14, 2015) ("a defendant will not be liable if 'the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product.'")

In *Harris v. McNeil Pharmaceutical*, 2000 WL 33339657, at *4 (D.N.D. Sept. 5, 2000), the plaintiff was himself a physician, who had become addicted to the defendant's drug. The plaintiff/physician's failure to read relevant drug warnings was fatal to his claims:

> Case law supports the proposition that a physician's failure to read the warnings, including package inserts and the Physician Desk Reference, essentially negates any possible liability on the part of [the manufacturer]. . . . [Plaintiff] testified that he does not recall reading the package insert, other than to scan its contents for dosage information. . . . Proximate cause is such an [essential] element. It is this court's opinion that [plaintiff's] failure to review the contents of the package insert . . . provided to him is fatal to his claims under all theories of liability.
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> *Id*. at *4-5 (citations and quotation marks omitted).

In *Pettit v. Smithkline Beecham Corp*., 2012 WL 3466978 (Pa. C.P. Philadelphia Co. June 12, 2012), "[the prescriber] repeatedly testified he could not recall ever reviewing the [drug's] label or PDR." *Id*. Summary judgment was appropriate because "when a physician fails to read or rely on a drug manufacturer's warnings, such failure constitutes the intervening, independent and sole proximate

cause of the plaintiff's injuries, even where the drug manufacturer's warnings were inadequate." *Id.* *See Nelson v. Wyeth*, 2007 WL 4261046 (Pa. C.P. Dec. 5, 2007) ("[defendant's] alleged failure to adequately warn could not have been the factual cause of [plaintiff's injuries] since the prescribing physician did not read nor rely upon any of [defendant's] warnings as contained in the label accompanying the prescription drug"); *Berry v. Wyeth*, 2005 WL 1431742, at *5 (Pa. C.P. June 13, 2005) (summary judgment granted based on failure to establish proximate causation when one physician failed to read the drug's labeling or the information in the PDR and the plaintiff failed to secure testimony from another prescribing physician that he had relied on the labeling to prescribe the drug to plaintiff).

Additionally, any allegation that Zydus did not make their label available is unsupported by any facts. Zydus' label has been published on federally run websites like Dailymed for the last decade.[12],[13]

There is no allegation that these physicians relied specifically on Zydus to provide a warning nor could there be since there is no legal obligation to specifically warn any individual physician. Such an argument is meritless as a matter of law,

[12] See Zydus' Amiodarone Prescribing Information on the federally-run Dailymed website at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b41cbcb5-9c5d-4e45-a4f2-952df5f22c00 (last visited October 27, 2021)

[13] Dailymed is a website operated by the U.S. National Library of Medicine to publish drug labels to health care providers.

and a product of "imaginative" advocacy that defies common sense. Zydus has no legal or ethical obligation to ensure the doctors read and understood the warnings.

C. Plaintiff Does Not Have A Legally Cognizable Action Based on Zydus' Purported Failure to Provide A Medication Guide

Plaintiffs' action based on Zydus' failure to provide a medication guide to plaintiffs had already been held by this Court to be preempted by federal law. *See* ECF No. 24. Plaintiffs have added no new facts or allegations to support this theory. This claim should again be dismissed as a matter of law.

Zydus has no duty, under state or federal law, to provide Medication Guides to patients. Plaintiffs cannot frame a meritorious cause of action for Zydus' alleged failure to deliver a Medication Guide. Given the "learned intermediary" defense, recognized in New Jersey and multiple jurisdictions whose law would apply, there can be no cause of action against a manufacturer for a purported failure to directly warn patients. Plaintiffs have also erred in formulating a regulatory duty that does not exist within the plain meaning of the medication guide regulation. The regulation only requires that a manufacturer either distribute, or make available, medication guides to distributors or authorized dispensers (pharmacies). The fact that plaintiffs allegedly did not receive a guide from their pharmacist does not evidence a breach by Zydus nor does that fact give rise to a claim.

The FDA's regulations do not require manufacturers to distribute Medication Guides to the patient. *See* 21 C.F.R. §208.24. These rules reflect the reality of the prescription drug industry, in which patients and manufacturers are separated by pharmacists and prescribing physicians. *See id*. Specifically, FDA's Medication Guide regulation states that:

> (b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either: (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.
>
> (e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) . . .

Id. (emphasis added). An "authorized dispenser" is "an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice," in other words a pharmacy or pharmacist, and not a drug manufacturer like Zydus. *Id*. Plaintiffs' concede "Zydus is a 'manufacturer' as defined by the

FDA." SAC ¶ 177. Thus, Zydus is not required by federal regulations to either deliver Medication Guides directly to or make Medication Guides available to patients.

Not only is this not required by the unambiguous wording of the regulation, it is impractical and unrealistic. It would be an impossible obligation given that the medication guide, passes through multiple stops in the supply chain before a pharmacist dispenses the drug to a patient. The plain meaning of the FDA regulation is a question of law for this Court and not a question of fact for the jury. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1680 (2019).

As multiple courts have recognized, this is "not the duty." *See Priest v. Sandoz, Inc.*, No. A-15-CV-00822-LY-ML, 2017 WL 7172504, at *12 (W.D. Tex. Dec. 28, 2017) *report and recommendation adopted*, No. 1:15-CV-822-LY, 2018 WL 582532 (W.D. Tex. Jan. 17, 2018) (holding that a manufacturer of amiodarone had no duty to provide medication guides to patients.). In reviewing and interpreting the federal regulations, the Western District of Texas determined that the only duty imposed upon a manufacturer, under 21 C.F.R. § 208.24(b), was the duty to provide the guides, or make them available, to distributors, packers, or dispensers. *Priest*, 2017 WL 7172504 at *12. The Western District rejected the argument that a manufacturer could nevertheless be liable, noting that "[p]laintiff, with no legal support, citation, or even argument, attempts to recast [the generic manufacturer's] duty as ensuring the

Medication Guide is actually given to the patient. However, that is not the duty." *Id.* at *12.

This holding was echoed in a second decision from the Western District of Texas. The district court held, "contrary to Plaintiff's contention, [the regulation] does not place a duty upon [the manufacturer] to take steps to ensure that the Medication Guides are distributed to patients beyond providing them in 'sufficient numbers' to distributors, packers, and authorized dispensers." *Mitchell v. Wyeth Pharm.*, Inc., 356 F. Supp. 3d 634, 638 (W.D. Tex. 2018); *see also Rusk v. Wyeth-Ayerherst Laboratories, Inc.*, 2015 WL 3651434 (W.D. Tex. June 11, 2015), *affirmed* 2015 WL 11050913 (W.D. Tex. 2015) (holding that it is the end distributor (or the pharmacy) who has the ultimate responsibility for providing the medication guides directly to the patient).

The Southern District of New York dismissed identical claims against a different generic manufacturer of amiodarone holding, "the regulation does not obligate a manufacturer to provide medication guides directly to patients or their agents." *Frei*, 2020 WL 1165975 at *11; *see also*, **Exhibit B**, *In re Amiodarone Cases*, No. JCCP 4956, at *5 (Cal. Sup. Ct., Alameda County November 14, 2019) (holding that manufacturers have no duty to provide medication guides directly to patients).

Having dispensed with any possibility that federal law imposes a duty on Zydus to directly deliver Medication Guides to patients or ensure pharmacies dispense them with their prescriptions, plaintiffs cannot instead pin their hopes on the existence of such an extensive duty under state law.

D. Plaintiffs' Causes of Action for Failure to Warn Are Expressly Preempted by Federal Law

Not only do plaintiffs' Medication Guide claims lack legal support, but along with all of plaintiffs' other causes of action, are impliedly preempted by federal law and must be dismissed. As held by the U.S. Supreme Court in *Mensing*, an action based on a generic manufacturer's failure-to-warn is preempted.

Preemption must apply because federal law obligates generic manufacturers to ensure their warnings are the same as those of the equivalent brand name drug product in all material respects. *See Mensing*, 564 U.S. at 624-25. Dozens of federal District Courts and Circuit Courts of Appeals have recognized that *Mensing* broadly preempts claims against generic drug manufacturers that attack the warnings, representations or disclosures a manufacturer makes about a generic drug's risks.

In fact, this Court, in addressing another products liability matter regarding a generic drug with a medication guide, has held that the plaintiffs "NJPLA claim is

preempted by federal law." *Nelson*, 2018 WL 1960441, at *13. Plaintiffs' action for failure to warn is subject to preemption.

Plaintiffs' causes of action for off-label promotion and failure to provide the Medication Guide exists by virtue of federal statutes and regulations and are impliedly preempted under 21 U.S.C. §337(a)'s prohibition on private enforcement of the FDCA and its regulations, as recognized in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *see also McDaniel*, 893 F.3d at 948 (affirming dismissal of preempted medication guide claims.).

1. Zydus is not legally responsible for third party representations regarding amiodarone

Plaintiffs seek to impose liability on Zydus on the basis of what third parties may have represented about the generic drug. Plaintiffs' allege that third party resources the Physician's Desk Reference and the Epocrates website/application contained "misleading and incomplete information about Amiodarone" (SAC ¶ 172) without citing the specific nature of the misstatements. Plaintiffs contend that Zydus had a duty to correct these unknown and unspecified misstatements. In addition, the plaintiffs contend that the brand, Wyeth, made misleading statements in an off-label marketing campaign on a third-party site that Zydus was obligated to correct.

There is no allegation of any Zydus misstatement or communication in writing or orally to anyone that would arguably constitute a Zydus deviation from its legally

imposed obligation of sameness regarding the labeling. As a matter of law, Zydus has no obligation nor ability to affirmatively go beyond the label and correct what others do or say regarding the product. *See Bean v. Upsher-Smith Pharms., Inc*., 2017 WL 4348330, at *10 (D.S.C., September 29, 2017) (holding that defendants could not have disseminated additional warnings regarding "off-label" use without violating federal law), aff'd, 765 Fed. Appx. 934 (4th Cir. 2019).

The United States Supreme Court has held that even if a generic manufacturer perceives there to be label inadequacies, there is no obligation for the generic manufacturer to withdraw from the market. *Mensing*, 564 U.S. at 644.[14]

Because these plaintiffs' actions are based on the contention that Zydus' labeling should have contained different or additional warnings, or that Zydus should have corrected other third-party statements about off-label use, the causes of action are preempted as required in the holding in *Mensing*, 564 U.S. at 616-24.

In *Mensing*, the Supreme Court determined that state law tort causes of action attacking the sufficiency of warnings provided by generic manufacturers are preempted by federal law. The overwhelming majority of state and federal courts, including the Third Circuit in *In re Fosamax (Alendronate Sodium) Prod. Liab.*

[14] As other examples of similar judicial holdings see, *Eckhardt v. Qualitest Pharmaceuticals Inc*., 858 F.Supp.2d 792, 801 (S.D. Tex. 2012); *Rojas v. Teva Pharmaceuticals USA*, Inc., 920 F.Supp.2d 772, 779 (S.D. Tex. 2013) (granting judgment on the pleadings for generic manufacturer on any claims based on the generics' failure to withdraw the generic drug from the market).

Litig. (No. II), 751 F.3d 150 (3d Cir. 2014), have recognized the impact of *Mensing*: no state law tort claims attacking a generic drug's warnings, representations, disclosures, or other marketing can survive federal preemption.[15] The Supreme Court reaffirmed and expanded *Mensing* in *Bartlett*, recognizing that preemption would apply to causes of action for design defect or those alleging a duty to withdraw a product from the market. *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466 (2013). Since *Bartlett*, more than 100 federal and state courts have dismissed virtually all products liability and tort claims against generic manufacturers as being subject to preemption.

The Third Circuit, in applying New Jersey law and following a detailed assessment of *Bartlett* and *Mensing*, held that a generic drug manufacturer "may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability." *In re Fosamax*, 751 F.3d at 163. Therefore, to the extent a generic drug manufacturer would need to undertake

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[15] *See, e.g., Houston v. United States*, 638 F. App'x 508, 513 (7th Cir. 2016) (affirming dismissal of a litany of products liability claims as preempted); *Guarino v. Wyeth*, 719 F.3d 1245 (11th Cir. 2013) (state warning claims are preempted); *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014) (affirming dismissal of failure to warn, design defect, and "stop-selling" as preempted); *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) (affirming dismissal of all claims); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674 (5th Cir. 2014) (same); *Moretti v. Wyeth*, 579 F. App'x 563 (9th Cir. 2014) (same); *Lashley & Del Valle v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014). (affirming all claims dismissed as preempted); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014) (same); *Moretti v. Mutual Pharm. Co.*, 518 Fed. App'x 486 (8th Cir. 2013) (affirming dismissal of warning claims as preempted).

any of those actions to comply with a purported state law, "that law is preempted by the FDCA." *Id*.

Federal law, therefore, preempts state law in three situations: "(1) when a federal statute includes 'an express provision for preemption'; (2) '[w]hen Congress intends federal law to 'occupy the field in an area of law; and (3) when a state and federal statue are in conflict.'" *Id*. at 158-159. New Jersey District Courts have taken this analysis and applied it to NJPLA to hold claims as preempted. *Nelson*, 2018 WL 1960441, at *13.

Numerous district courts have granted motions to dismiss causes of action for in cases involving the exact same product—generic amiodarone—when presented with similar allegations.[16]

In *Rusk*, the court addressing similar causes of action regarding amiodarone, found the failure-to-warn action preempted as a matter of law. Likewise, in *Stephens*, the court held per *Mensing* that the cause of action for failure-to-warn is "wholly preempted by federal law," and plaintiff could not "sue a generic manufacturer on a failure to warn claim or a state law design defect claim that turns on the adequacy of

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[16] *See Rusk*, 2015 U.S. Dist. LEXIS 179113 (granted in part); *Stephens v. Teva Pharm. Inc.*, et al., 70 F. Supp. 3d 1246, 1254 (N.D. Ala. 2014) (dismissing all claims with prejudice); *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 851 (E.D. N.C. 2016) (dismissing all claims with prejudice); *Elliott v. Sandoz, Inc.*, No. 2:16-CV-00861-RDP, 2016 WL 4398407 at *9 (N.D. Ala. Aug. 18, 2016) (granted in part); *McLeod v. Sandoz, Inc.*, No.: 4:16-cv-01640-RBH, 2017 WL 1196801 at *7 (D.S.C. Mar. 31, 2017) (dismissing medication guide and products liability claims as preempted); *Tutwiler*, 2017 WL 3315381 (dismissing medication guide claims as inconsistent with learned intermediary doctrine and preempted).

a drug's warnings." *Stephens*, 70 F. Supp. 3d at 1250. Most recently, in *Frei*, the court cited *Mensing* to dismiss the same cause of action for failure-to-warn that is pled in this action regarding a generic amiodarone. 2020 WL 1165975, at *5. Plaintiffs' action in the case at bar is similarly preempted.

2. Plaintiffs' Off-Label Promotion and Medication Guide Claims Are Impliedly Preempted

Separate and apart from *Mensing* preemption, plaintiffs' causes of action are subject to implied preemption under 21 U.S.C. §337(a) because they are premised upon violations of federal duties that only the federal government may enforce. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). In *Buckman*, the Supreme Court cited 21 U.S.C. § 337(a) to hold "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with the [law]." *Id.* Where "the existence of these federal enactments is a critical element in [plaintiff's] case," and where a plaintiff's claims "exist solely by virtue of the FDCA . . . requirements," state law claims are impliedly preempted by the FDCA. *Id.* at 352. While plaintiffs plead both an action for off-label promotion and for failure to provide Medication Guide against Zydus, both causes of action are dependent upon, and exist solely by virtue of the FDCA's restrictions on Zydus as a manufacturer, and thus are impliedly preempted.

Plaintiff has not identified any other state statute prohibiting drug manufacturers from promoting their products for off-label uses. Plaintiff's cause of action is legally deficient since it is based only on the argument that Taro's alleged off-label promotion contravened FDCA and FDA regulations.

Thus, because plaintiffs' off-label promotion claims are based on alleged violations of the FDCA and its regulations, they are impliedly preempted under *Buckman* and 21 U.S.C. §337(a). *See, e.g., Perdue*, 209 F. Supp. at 852 ("The restrictions and guidelines placed upon pharmaceutical companies for off-label promotion are entirely dependent upon the statutory and regulatory scheme created by the FDCA," and thus such claims are impliedly preempted.); *Frei*, 2020 WL 1165975 at *6 (holding "off-label use and promotion are subject to preemption under *Buckman* as well" because those duties exist solely by means of the FDCA).

"The duty of the Defendant to provide Medication Guides to *pharmacies* (i.e., 'distributors, packers or authorized dispensers') arises solely under federal law," and thus *Buckman* preemption applies. *Elliott*, supra, 2016 WL 4398407, at *6 (emphasis in original). Plaintiffs cannot privately enforce the regulations requiring manufacturers to distribute or make available Medication Guides, and claims premised upon alleged failure to comply with federal regulations governing Medication Guides should be dismissed as impliedly preempted. *See id*.

In *Frei*, the Southern District of New York recently dismissed an action for both off-label promotion and failure to provide Medication Guide as impliedly preempted pursuant to *Buckman* and 21 U.S.C. §337(a). *Frei*, 2020 WL 1165975 at *3-*6. *Frei* first recognized plaintiffs' claims would force the generic amiodarone manufacturer to "violat[e] its federal duty of sameness, as well as plaintiffs' attempts to enforce FDA regulations." *Id*. at *4. The court in *Frei* noted it would be impossible for a generic drug manufacturer, bound by the federal duty of sameness, to also comply with the state law duties plaintiffs assert, but even if the duties were parallel, plaintiffs' claims would still be an attempt to privately police compliance with the FDCA and its regulations, which also renders them preempted. *Id.* at *4-5.

In addressing Medication Guide claims, the court in *Frei* recognized that the regulations required that manufacturers "provide medication guides in sufficient numbers, or the means to produce them in sufficient numbers, to distributors, so that such distributors could in turn provide the medication guides to patients. Critically, the regulation *does not* obligate a manufacturer to provide medication guides directly to patients or their agents." *Id*. at *5 (emphasis added). The court concluded that, despite couching claims under state law, "it is clear the existence of the FDA's medication guide regulation is the gravamen of these claims" and is therefore preempted by *Buckman*. *Id*. Here too, it is undeniable that plaintiffs' claims are

focused on the existence of Medication Guide regulations that are federal in nature and must be dismissed.

E. PLAINTIFFS' CAUSES OF ACTION ARE INSUFFICIENTLY PLED

Plaintiffs fail to plead their claims with the factual support required by Fed. R. Civ. P. 8(a) and 8(a)(2) or the heightened pleading with particularity standard for fraud-based claims required by Fed. R. Civ. P. 9(b).

The SAC is comprised of speculative and conclusory statements absent the necessary factual allegations about Zydus' conduct to support such conclusions. Plaintiffs have only generally alleged that various manufacturers either engaged in or benefited from off-label promotion or otherwise failed to warn the plaintiffs of the risks of amiodarone, but the SAC lacks specificity regarding the acts or omissions allegedly committed by Zydus.

For instance, when or where such actions occurred, or how they impacted any particular plaintiff physician in the prescribing decisions is absent. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and where the court cannot infer more than mere possibility of misconduct, the complaint has not "show[n] that the pleader is entitled to relief." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007).

As an example of the less than diligent assertion of facts, plaintiff Cecil Thomas allegedly received 400 mg tablets of amiodarone. Yet Zydus does not manufacture or distribute 400 mg tablets of amiodarone. Zydus only manufactured, distributed, and received FDA-approval for 200 mg amiodarone tablets. Therefore, it is impossible that plaintiff Cecil Thomas received 400 mg tablets of amiodarone manufactured by Zydus.

The SAC alleges that plaintiffs were prescribed amiodarone as early as 2000 and up through 2019 as a result of Wyeth and Zydus' promotional efforts. Yet, Zydus did not enter the amiodarone market until after receiving its FDA approval in September 2008. This demonstrates that as with the original complaint plaintiffs continue to allege generalized claims with no focus on Zydus, Zydus' specific actions or any specific statements made by Zydus.

While plaintiffs have abandoned their cause of action for Fraud in the SAC, various allegations nevertheless are premised on legally unsupported and improperly pled fraud. To the extent plaintiffs continue to allege that Zydus' alleged conduct was fraudulent, plaintiffs fail to meet the heightened pleading standards required under Fed. R. Civ. P. 9(b) for fraud-based claims, instead pleading in conclusory fashion only that "Manufacturers of amiodarone also provide false and/or misleading information to various sources used by physicians when contemplating prescribing a drug for an off-label use." SAC ¶ 175, without detailing where, when or how.

While plaintiffs have alleged that information was concealed or misrepresented, plaintiffs glaringly fail to allege specific acts of concealment or misrepresentation by Zydus, receipt of a representation or act of concealment by any prescribing physician that influenced the decision to prescribe amiodarone to any plaintiff, or the other necessary elements that must be pled with particularity as to Zydus.

A complaint must contain a "plain statement of the claim showing that the pleader is entitled to relief, in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 554 (internal quotation omitted). Dismissal is warranted if a complaint merely contains "naked assertions devoid of further factual enhancement," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), or "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555.

Not only does the SAC contain conclusory allegations and legal recitations devoid of factual support, the allegations do not even rise to the level of plausibility. Plaintiffs do not specify the dates on which they received amiodarone prescriptions, the pharmacies where they were filled, or other minimal details regarding their respective allegations that adequate warnings in the form of Medication Guides were not provided with their prescriptions. Moreover, plaintiffs generally allege that Zydus should have been made aware of statements made on PDR and Epocrates but do not identify what statement, when it was published, and where it was published. This lack

of basic facts is inadequate under Fed. R. Civ. P. 8(a) and these actions should be dismissed.

The action for off-label promotion against Zydus, based on the alleged conduct of brand manufacturer Wyeth, cannot springboard into generalized, conclusory allegations of off-label promotion against Zydus as a supposedly willing beneficiary of Wyeth's conduct (which they deny). *See e.g.* SAC ¶¶ 157, 177

The SAC alleges that Zydus concealed information, deceived physicians, participated in illegal off-label promotion. SAC ¶¶ 172, 183, 184. Yet, plaintiffs have failed to identify at least one specific instance where Zydus promoted amiodarone for off-label use or any warning every issued to Zydus by the FDA.

The SAC's off-label promotion allegations sound in fraud to the extent they assert Zydus concealed and failed to disclose information regarding the approved indications for use of amiodarone, and misrepresented the safety of use of amiodarone for other conditions, and are therefore subject to the heightened pleading requirements of Rule 9(b).

To properly plead a claim sounding in fraud, a complaint must provide the "who, what, when, where and how" of the alleged fraudulent conduct. *In re Plavix Mktg., Sales Practice & Prod. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927, 938 (D.N.J. 2017). Throughout the nearly identical amiodarone lawsuits that have been dismissed across the country, courts have recognized the cause of action for off-label promotion

sounds in fraud and have underscored that it must be pled with requisite particularity of Rule 9(b). The same is true here. Beyond generic and conclusory references to Zydus, plaintiffs have not pled a specific individual or agent of Zydus who made the purported promotional statements to answer the "who" element, the FAC also does not identify: (1) what about the purported off-label promotion statements was fraudulent, false or misleading; (2) when these statements were made; (3) where or how they were made or disseminated; or (4) to whom they were made.

Similarly, the SAC makes conclusory and vague allegations that Zydus "did not provide the FDA warnings for generic amiodarone for publication in the physical PDR any time after 2007." SAC ¶ 163. The SAC alleged that "both the PDR and Epocrates contain misleading and incomplete information about Amiodarone, which deceives physicians…" SAC ¶ 172. Plaintiffs assert Zydus concealed dangerous problems and "engaged in a conspiracy with Wyeth and other generic drug manufacturers to suppress material facts from all Plaintiffs." SAC ¶ 157.

However, plaintiffs do not allege a *single instance* in which Zydus engaged in any deceptive, misleading or off-label promotional campaigns for amiodarone. Consistent with the amiodarone medication guide litigation, the Court should dismiss these claims as insufficiently pled.[17]

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[17] *Mitchell v. Wyeth Pharm., Inc.*, No. A-16-CV-574-LY-ML, 2017 WL 7361751, at *5 (W.D. Tex. Jan. 19, 2017), *report and recommendation adopted*, 2017 WL 7361750 (W.D. Tex. Feb. 9, 2017); *McDaniel v. Upsher-Smith*

F. PLAINTIFFS' CAUSES OF ACTION ARE BARRED BY THE APPLICABLE STATUTES OF LIMITATIONS

Ninety percent of plaintiffs' claims (181 plaintiffs) are time-barred by their respective state's statute of limitations and are subject to dismissal. Two plaintiffs – Cecil Thomas and Debbie Thomas – alleged that Cecil was prescribed 400 mg of amiodarone by his physician. SAC, ¶ 89 (d).

When the allegations of a complaint demonstrate that an action is barred by the applicable statute of limitations, a defendant may raise the affirmative defense in a pre-answer motion to dismiss. *Simmons Oil Corporation v. Bulk Sales Corporation*, 498 F.Supp. 457, 460 (D.N.J. September 3, 1980). That is the case with the SAC. One-hundred and eighty-one (181) of the total two-hundred and one (201) plaintiffs have actions that are time-barred under their applicable state law. Attached as **Exhibit D** is a spreadsheet identifying each plaintiffs' residence, date of injury, and each state's applicable statute of limitations for the claims alleged.

In light of these facially time-barred claims, plaintiffs fail to satisfy their burden to plead facts sufficient to establish that the statutes of limitations should be tolled. Plaintiffs contend in the SAC that Zydus should be estopped from asserting a limitations defense because it allegedly conspired with Wyeth to conceal facts

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Pharm., Inc., 229 F. Supp. 3d 707, 713 (W.D. Tenn. 2017), *aff'd on other grounds*, 893 F.3d 941 (6th Cir. 2018); *Elliott v. Sandoz* Inc., 2016 WL 4398407, at *8.

about amiodarone. SAC ¶ 186. This is nothing more than speculation. Accordingly, the claims should be dismissed with prejudice.

G. PLAINTIFFS HAVE FAILED TO JOIN NECESSARY PARTIES AND THERE ARE DUPLICATIVE CLAIMS IN OTHER JURISDICTIONS

Most of the plaintiffs in this lawsuit (86%) have filed a nearly identical lawsuit against other generic manufacturers of amiodarone in other courts simultaneously, asserting the same alleged injuries, damages, and request for relief asserted here. This issue presents a risk of double or even triple recovery. Plaintiffs have failed to join necessary parties that could have contributed or been the proximate cause of plaintiffs' alleged injuries. While plaintiffs have all joined in a lawsuit together against Zydus, these are individual claims based on individualized facts and injury. If there are other potential tortfeasors that could have contributed or been the proximate cause of the alleged injuries – assuming plaintiffs' claims are even viable – then necessary parties should be joined and plaintiffs should not be permitted to have multiple suits pending around the country arising out of the same facts and injury.

Upon information and belief, in each of these actions, plaintiffs have ingested, over a given period of years, amiodarone manufactured by numerous manufacturers. In each instance the plaintiffs have argued that the respective manufacturers failed to ensure that the mediation guides were distributed to the plaintiffs. Plaintiffs will therefore likely argue that there has been a history of use of amiodarone from different

manufacturers over an expanded time period, each purportedly failing to provide a medication guide. To the extent that plaintiffs will contend that their injuries are cumulative and result from the amiodarone ingested over these years, each manufacturer (assuming liability from the non-distribution of the guides) may have a share of fault. These parties all become necessary parties for allocation and contribution – all as well to avoid each plaintiff's duplicative recovery.

It, as well, wastes this Court's resources as well as Zydus'. "[I]t is fundamental that no matter under what theories of liability may be established, there cannot be any duplication of damages." *P. v. Portadin*, 432 A.2d 556, 560 (N.J. App. Div. 1981). Indeed, "common law prohibits a double recovery for the same injury." *Ptaszynski v. Atl. Health Sys., Inc.*, 111 A.3d 111, 120 (N.J. App. Div. 2015).

From time to time in pharmaceutical mass tort and multidistrict litigation, some plaintiffs have either inadvertently or intentionally filed duplicative lawsuits asserting the same injury. These duplicative filings are generally not allowed to proceed, but instead courts encountering these situations generally have rectified them through either dismissal or stay of the later-filed actions so that defendants are not required to expend resources defending a lawsuit that may be adjudicated completely in the earlier-filed court. This Court should do the same here.

V. CONCLUSION

For the foregoing reasons, Zydus respectfully request that this Court dismiss all of Plaintiffs' claims under Fed R. Civ. P. 12(b)(6). Because amendment would be futile, Zydus requests dismissal with prejudice.

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Respectfully submitted,

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